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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,769	05/31/2001	Dennis M. Brown	A-70600/RFT/AMS	1226

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FLEHR HOHBACH TEST
ALBRITTON & HERBERT LLP
4 Embarcadero Center - Suite 3400
San Francisco, CA 94111-4187

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/872,769

Applicant(s)

BROWN, DENNIS M.

Examiner

Sharmila S. Gollamudi

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 23 October 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Applicant argues that there is not reason to modify the primary reference to arrive at instant invention. Applicant argues that Francis only teaches the presence of galactitol to stabilize the therapeutic agent. It is argued that nowhere does Francis address the ability of the composition to act as an antiproliferative. Applicant argues that although Levin teaches an antiproliferative agent and DAG for brain tumors, the disclosure is ambivalent in nature and does not disclose specific agents.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that Francis teaches the instant galactitol (DAG) with cisplatin, which is the instantly claimed antiproliferative agent. Secondly, the examiner points out that on column 3, lines 60-65, Francis teaches utilizing a ratio of galactitol to agent of 1.05:1. The instant claim recites, "in an amount sufficient to modulate said cellular proliferative disease." The examiner points to page 6 of instant specification wherein applicant states:

In one embodiment, hexitols of the invention are administered at a dosage of between 0.2 mg/kg and 20 mg/kg. In a preferred embodiment, the administration of hexitols is at a dosage of between 0.5 mg/kg and 15 mg/kg. In a more preferred embodiment, the dosage is between 0.5 mg/kg and 10 mg/kg. In an even more preferred embodiment, the hexitols are administered at a dosage of between 1 mg/kg and 5 mg/kg. The antiproliferative agents of the invention also may be administered within a range of suitable dosages. For example, cisplatin may be administered at a dosage between 0.2 mg/kg and 7.5 mg/kg. More preferably, cisplatin is administered at a dosage between 0.5 mg/kg and 5 mg/kg. Even more preferably, cisplatin is administered at a dosage between 1 mg/kg and 4 mg/kg.

The applicant states that the hexitol dosage is 1 mg/kg and 5 mg/kg and the cisplatin is 1 mg/kg and 4 mg/kg, it should be noted this dosage ratio is near Francis's about 1:1 range. Therefore, it is clear that Francis utilizes the same "effective amount"

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as the instant invention and thus the prior art DAG will implicitly act as an antiproliferative agent since it is utilized in the same amount as instant invention.

Therefore, Francis teaches the entire invention. Levin is relied upon to demonstrate that it is known in the art that DAG can act as an antiproliferative agent and shows that enhanced activity of an antiproliferative agent and galactitol. The examiner points out that the newly discovered function or property of a component that is inherently possessed by the prior art, is not distinguishable over the prior art. See *In re Best*. In instant case, Francis not only teaches the instant galactitol but also teaches it in the same amount as the applicant. Therefore, galactitol would inherently act the same as the instant invention. Furthermore, it cannot even be said that applicant has found a new function since clearly Levin teaches that DAG is not only utilized as an antiproliferative agent "since it has a cell killing moiety" but also its anti-tumor activities are enhanced with the addition of another antiproliferative agent.

In regards to the argument that Francis and Levin are not in the same field of endeavor, the examiner points out that when a skilled artisan incorporates an antiproliferative agent in a pharmaceutical composition, it is obvious the composition will be utilized to treat proliferative diseases. The name "antiproliferative agent or anti-cancer agent" implicitly states the function. Therefore, since Francis teaches cisplatin and DAG together in a composition, it is obvious that one would use the composition to treat proliferative diseases. Levin also teaches DAG and an antiproliferative agent which is utilized for chemotherapy. It is quite clear that both references are in the art of endeavor.

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Therefore the rejection is maintained.

yes

Michael G. Hartley
MICHAEL G. HARTLEY
PRIMARY EXAMINER